Workgroup 3

International Aspects of PT Programs

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WHAT ARE SOME OF THE DIFFICULTIES IN PROVIDING RELEVANT PT/EQA SAMPLES ACROSS INTERNATIONAL OR INTERCONTINENTAL BOUNDARIES?

- Transportation issues:
  - Specimen integrity
  - Border barriers
  - Time lag
- Suggest reverse PT cycle, where participant sends sample to PT provider?

- Transport into and within countries is hampered by policies and regulations (IATA, etc)
  - difficulties clearing borders - customs, health officer
- Need:
  - Endorsement from top levels of government
  - International Organization (WHO) to develop a standardized system for transporting specimens, eg:
    - diplomatic pouch
    - obtaining a special exemption from the Ministries of Health within countries
    - suggest labeling specimens as EQA, not diagnostic, specimens
    - address to hospital/research institute (non-commercial sites)
    - No customs duty (EQA specimens, not IVDs)
- Suggest approaching WHO simultaneously through regional organizations and international meetings

- Communication:
  - Different reporting units
  - Language - use UN official languages
  - Notification - of specimen despatch & receipt
  - Motivation - plaques/certificates
- Need multiple communication channels:
  - Internet, email, listserv, fax, telephone, PDA
- Lack of SOPs for transportation and communication
  - Regional or international organizations develop standard distribution procedures.
  - Focal person to handle communication and specimens
- Fees:
  - Developing country funding from international NGOs

IN WHAT CONTRIES OR REGIONS ARE NATIONAL REGULATIONS CREATING NON-TARIFF BARRIERS THAT INHIBIT INTERNATIONAL COOPERATION ON PT/EQA PROGRAMS?

- Industrialised countries
  - Less likely to cooperate
  - National regulations hinder or prevent:
    - legal, licensing, accreditation
    - commercial, market
    - autonomy
  - Bring PT providers together to establish consensus (?funding needed)

- Developing countries
  - More enthusiastic to collaborate
  - Lack infrastructure
    - need for workforce development
    - develop core leadership nucleus for EQA
  - Lack of (appropriate) standards
    - Standards must be appropriate to country's situation
    - Establish ideal and minimum standards
  - How do we translate these ideals into a practical action plan?

WHAT ARE SOME OF THE TRANSPORT ISSUES INFLUENCING INTERCONTINENTAL USE OF PT/EQA PROGAMS AND MATERIALS?

- Due to time and temperature issues it is essential that the samples be transported efficiently

How Might These Issues Be Resolved?

- Selection of courier / distributor
  - work with regional couriers, establish relationships with individuals
  - consider shipment to one point, for distribution throughout an individual country
- Proper training of shipping personnel
  - includes correct classification of product that is to be shipped
- Endorsement that specimens tested to transfusion standard are biological materials, exempt from dangerous goods' labelling & packaging rules
- International organization to work as advocate
  - WHO; this conference; any other international group

CAN INTERNATIONAL PEER GROUPS OF PT/EQA PROGRAMS BE DEFINED? If SO, HOW?

- In some cases peer groups would be appropriate. They might be defined according to:
  - Purpose (Educational vs. Regulatory)
    - very important distinction
    - must be defined up-front
  - Type of testing
  - Clusters of similar lab type:
    - reference labs; rural labs; out-post labs

WHAT FACTORS NEED TO BE DEFINED TO ALLOW PT/EQA INFORMATION TO BE EXCHANGED IN A COMPARABLE MANNER BETWEEN INTERNATIONAL LABORATORY GROUPS?

- Each provider needs to define:
  - The question they ask the participant
  - The data they require
  - How the data is processed
    - Formulation of the specimen
    - Assessment model
  - The purpose of the scheme
    - Licencing
    - Accreditation
    - Education

WHAT FACTORS NEED TO BE DEFINED TO ALLOW PT/EQA INFORMATION TO BE EXCHANGED IN A COMPARABLE MANNER BETWEEN INTERNATIONAL LABORATORY GROUPS?

- International exchange of EQA information should be at the level of transfer between:
  - EQA providers
  - Reference laboratories (should also be participants)
  - Manufacturers (should also be participants)
  - Regulatory bodies
  - Licensing bodies

WHAT FACTORS NEED TO BE DEFINED TO ALLOW PT/EQA INFORMATION TO BE EXCHANGED IN A COMPARABLE MANNER BETWEEN INTERNATIONAL LABORATORY GROUPS?

- Report format as provided to participant
  - Language
  - Detail
  - Format of report (use of tables, histograms etc)
  - Personalised advice (small schemes)

WHAT PROCEDURES EXIST THAT CAN FACILITATE INTERNATIONAL COOPERATION BETWEEN PT/EQA PROGRAMS?

Coalition

Priority setting
Advocacy
Financial justification

- Meetings
- Publication (Newsletters of EQA providers, Product specification Discipline specific)
- Ongoing assessment of programs (scheme by scheme and outcome of benefits to participants)
- Training
- Internet
- Exchange of written and material standards
- Marketing
- Workshops
- Exchange programs
- Mentoring
- Network information (inventory of EQA scheme providers, comparable databases)

Collaborative Activities ⟷ Communication

WHAT PROCESSES ARE IN PLACE TO FACILITATE PT/EQA FOR LOW VOLUME OR "ORPHAN" ASSAYS? WHAT NEW PROCESSES WILL NEED TO BE DEVELOPED?

- Information sharing and education
  - Assay providers (DORA, AssayFinder) and schemes
  - Enhance existing websites
  - Create new websites (?'meta-sites')
- Methods of coordination
  - Professional societies
  - Industry
  - Government
- Validation of methods
  - Availability of global guidelines
  - Round Robins
  - Performance criteria
  - Accreditation

WHAT CRITERIA SHOULD BE USED FOR SELECTION AND PROVISION OF PT/EQA PROGRAMS INTERNATIONALLY?

- Voluntary EQA
  - Follow ISO Guide 43-1 requirements
  - Review WHO guidance against ISO 43-1
- Regulated EQA
  - Accreditation to requirements such as ILAC G13, CPA

FOR WHAT TYPES OF LABORATORY TESTING WOULD IT BE BETTER TO RE-ANALYZE PATIENT SPECIMENS RATHER THAN SENDING OUT SAMPLES TO DETECT POOR LABORATORY PERFORMANCE? WOULD THIS BE A BETTER INDICATION OF ACTUAL LABORATORY PERFORMANCE?

- No tests could be better evaluated by reanalysis on an international PT scope
  - This may be an approach to standardization, but not reasonable for inter-laboratory evaluation on an international scale

- Other mechanisms may be useful, such as:
  - "virtual lab"/ "clone lab" – laboratorians travel to central laboratory and test specimens – this would be mechanism for education rather than PT
  - "virtual" challenges: use of the internet to send pictures or raw data for analysis, for example
  - questionnaires – could evaluate pre- and post-analytic processes as well as analytic
  - use of manufacturers' QC programs on a regional or international scope

- Reanalysis may be valuable on a regional scope or through a hierarchical process
  - Tests for which accuracy is more important than precision, would be better for re-analysis (e.g. serology, histopathology, microscopic urinanalysis) than tests for which precision is more important than accuracy (e.g., chemistry, hematology)
  - On regional level, could send specimens to a central laboratory with accepted credibility; adds element of traceablility
  - Could use multi-layer approach from laboratories, to regional level to international level

HOW WOULD THE COST COMPARE WITH TRADITIONAL PT/EQA AND WHAT WOULD BE THE LOGISTICAL CONCERNS ABOUT ESTABLISHING A RE-EXAMINATION OF PATIENT SPECIMENS?

- Re-examination would cost more than traditional PT
- Alternative mechanisms described above may cost less
- Logistical concerns include:
  - Language
  - Population variance and incidence of abnormals
  - Access to internet
  - Ethics/laws/cultural issues
  - Shipping

Summary

- Specimen transport is a major concern
  - without specimens, all else is irrelevant!
  - individual schemes (or coalition) insufficient influence
  - WHO & international level support needed
- Need to define scheme purpose
  - otherwise, cannot know if fit for purpose
- Enhanced communcation required
  - variety of means must be used
- Schemes shold comply with recommendations and accreditation
- Novel means of EQA should be explored

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